K003954

JUL 1 2 2001

510(K) Summary

(1)	**Submitter's name:**	Biocomposites Ltd
	Submitter's address:	Etruscan Street, Etruria, Stoke-on-Trent, ST1 5PQ, England
	Submitter's telephone number:	44 (0) 1782 206500
	Contact person:	Stephen Bratt
	Date summary prepared:	12th April 2001
(2)	**Trade or proprietary device name:**	Stimulan® Calcium Sulfate Bone Void Filler Kit
	Common or usual name:	Calcium Sulfate
	Classification name:	Unknown
(3)	**Legally marketed predicate device:**	Wright Plaster of Paris Bone Void Filler Kit

(4) **Subject device description:**

Stimulan® Calcium Sulfate Bone Void Filler Kit is provided sterile for single patient use. The biodegradable, radiopaque pellets are resorbed in approximately 30 - 60 days when used in accordance with the device labelling. Stimulan® is manufactured from medical grade calcium sulfate hemihydrate ($CaSO_4$ - $\frac{1}{2}H_2O$) powder and a saline mixing solution.

(5) **Subject device intended use:**

Stimulan® pellets are indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure.

Stimulan® pellets are indicated to be gently packed into bony voids or defects of the skeletal system (i.e. long bones, extremities, spine and pelvis). Pellets should not crushed, shaved or cut.

The bony defects or cavities may be surgically created or the result of traumatic injury. Stimulan® pellets provide a bone graft substitute that resorbs and is replaced with bone during the healing process.

Stimulan® is biodegradable and biocompatible and may be used at any infected site.

Stimulan® is manufactured from medical grade calcium sulfate and mixing solution in premeasured quantities that resorbs and is replaced with bone during the healing process. Also, as the implant is biodegradable and bicompatible, it may be used at an infected site.

(6) **Technological characteristics:**
Stimulan® has the equivalent technological characteristics (i.e. chemical composition, mechanical strength and dissolution rate performance) as the predicate device.

(7) **Performance data:**
Testing demonstrated that Stimulan® has equivalent dissolution, mechanical and mass to volume ratio characteristics to the predicate device. Testing indicated that the product is non-pyrogenic.

(8) **Basic for substantial equivalence:**
Stimulan® is safe and effective because it is equivalent to the predicate device in terms of chemical composition, indications for use, and product performances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Mr. Stephen Bratt
Managing Director
Biocomposites Ltd.
Etruscan Street, Etruria, Stoke-on-Trent
Staffordshire, ST1 5PQ, England

Re: K003954
Trade/Device Name: Stimulan – Calcium Sulfate Bone Void Filler Kit
Regulatory Class: Unclassified
Product Code: MQV
Dated: April 12, 2001
Received: April 17, 2001

Dear Mr. Bratt:

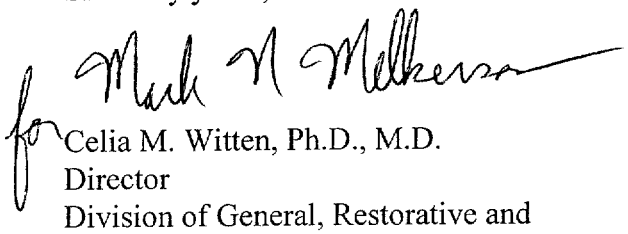
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K003954

Device Name: Stimulan® Calcium Sulfate Bone Void Filler Kit

Indications For Use:

Stimulan® pellets are indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure.

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The bony defects or cavities may be surgically created or the result of traumatic injury. Stimulan® pellets provide a bone graft substitute that resorbs and is replaced with bone during the healing process.

Stimulan® is biodegradable and biocompatible and may be used at any infected site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003954

(Optional Format 3-10-98)